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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,000	08/01/2000	Bruce Tockman	279.246US1	8111

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/630,000

Applicant(s)

TOCKMAN ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-46 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/03 has been entered.

Election/Restrictions

Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 5.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term “coradial” is not used in the specification.

Claim Rejections - 35 USC § 112

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter not described in the original specification is the lead body including two or more “coradial” conductors, wherein the coradial conductors are wound about a

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single axis, in combination with the other elements in the claims. The original specification only states that the conductors are “each wound together”. Conductors may be wound together, but not have the same radius or axis. Nothing in the specification relates to the conductors being “coradial”. This rejection is related to new matter.

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described is the lead body including two or more “coradial” conductors, wherein the coradial conductors are wound about a single axis, in combination with the other elements in the claims. This rejection is related to enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the term “coradial” is vague. It is unclear what “coradial” means since it is not defined or used in the specification and since it can not be found in a dictionary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20, 24, 26, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelsson et al (6249708).

Nelson discloses the claimed invention and the use of different types of conductors, (multifilar, unifilar, any combination of the two, DBS) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, it is inherent that the different conductors will have different electrical properties.

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Claims 21-23, 25, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.

Nelson discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the first conductor disposed only in the second and third sections (claims 23 and 44). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson with the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors and the termination of the first conductor at its respective electrode and connector as taught by Nelson in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead and provide the needed length of the first conductor to provide electrical therapy or sensing to the electrode.

Therefore, it would have been an obvious matter of design choice to modify Nelson to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat

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setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration.

Claims 16-20, 24, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al (5935159).

Cross discloses the claimed invention and the use of different types of conductors, (stranded, coiled, having different diameters) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section. Also, it is inherent that the different conductors will have different electrical properties and that the con.

Claims 21-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr et al.

Cross discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors

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having a heat setting capability (claim 25), and the lead having a two or three dimensional bias. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Cross with the first material being MP35N and the second material being Pt/TA, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors as taught by Cross in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead.

Therefore, it would have been an obvious matter of design choice to modify Cross to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities and the lead having a two or three dimensional bias since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration and since it was known in the art that leads are provided with a two or three dimensional bias to allow the lead to be easily located in a particular part of the body and allow the lead to remain in that location.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. In addition, the arguments that "the meaning of 'coradial' is apparent from the specification" for the 112 first paragraph rejection and that "coradial" is reasonably ascertainable from the specification for the 112 second paragraph rejection and lack of antecedent basis for claim terminology are not persuasive since the figures show and the specification describes only the conductors being wound together, and it can not be determined if they are "coradial". US patents 6253111, 4640983, and 6400992, are three teachings of many that show the use of different conductors having different stiffness used in medical leads.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

GRE
August 10, 2003


GEORGE R. EVANISKO
PRIMARY EXAMINER

8/10/3